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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/488,103 01/20/00 STARK

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EXAMINER

HM22/0921

JOYNES, R

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

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09/21/01

Elan Holdings Inc
1300 Gould Drive
Gainesville GA 30504

**Please find below and/or attached an Office communication concerning this application or
proceeding.**

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/488,103

Applicant(s)

STARK ET AL.

Examiner

Robert M. Joynes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) 26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment filed on July 2, 2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10-14 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-14 and 28-30 recite the limitation "said polymers" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. There are no limitations in the claims prior to these claims or in the claims upon which they depend that requires multiple polymers. The claims prior to Claims 14 and 30 recite the required polymer in singular fashion. Therefore these claims lack antecedent basis for reciting the limitation of "said polymers". Claims 12, 13, 28 and 29 recite "the or each polymer" is a defined polymer. These claims also lack antecedent basis because nowhere prior to these claims or in claims from which they depend are multiple or mixed polymers required as the coating for the core. Therefore, by reciting "the or each" applicants is suggesting that one or more polymers is suggested prior to the listed claims.

Claim 10 recites that the polymeric coating contains a major portion of a film-forming polymer. Claim 11 recites that the polymeric coating contains a minor portion of

a film-forming polymer. It is unclear what applicant is trying to convey by reciting limitations of "major" or "minor" portions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-8, 10-25 and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Buseti et al. (WO 98/32426). Buseti et al. teaches a multiparticulate formulation comprising a core of a drug or its pharmaceutically acceptable salt surrounded by a polymeric coating (Col. 2, lines 22-29). The polymeric coating is effective to achieve an initial lag between administration of the formulation and the release of the drug *in vivo* of at least 4-9 hours, but the lag time may be longer or shorter in certain cases (Col. 11, lines 1-10). Buseti et al. teaches that the drug may be a wide variety of drugs but specifically the drug may be a beta-blocker such as bisoprolol fumarate (Col. 6, lines 8-11). Prior to the coating of the polymeric coating, a first layer of polymers is applied to the core (Page 11, lines 25-31). The polymers of the first layer include hydroxypropylmethylcellulose, hydroxypropyl cellulose, hydroxypropyl ethylcellulose and xanthan gum (Page 12, lines 1-7). The polymeric coating (second layer) is then applied to the core (Page 12, line 24 – Page 13, line 9). The polymers of

this second layer include methacrylic acid copolymers, vinyl polymers and cellulosic polymers (Page 13, lines 10-18).

The polymeric coating further contains excipients, filler, plasticizers, lubricants, flow promoting agents, colorants and flavorants (Page 14, lines 19-28). These additional ingredients are present in amounts of 10% or less based on the total dry weight of the polymer (See examples on pages 17-24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 10-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Busetti et al. The teachings of Busetti et al. are discussed above.

Busetti et al. does not specifically teach a lag period of at least three hours but does teach a lag period of 4-9 hours stating that the period may be shorter or longer (Col. 11, lines 1-10). Busetti et al. also does not specifically teach bisoprolol hemifumarate as the drug but does teach bisoprolol fumarate as an acceptable drug for the formulation. The exact range percentages of the excipients present in the polymeric coating and the exact ranges for the weight percent of the polymeric coating present in the total composition weight are not expressly taught by Busetti et al. The reference does teach that multiple layer can be coated onto the cores to vary the lag time prior to the delivery of the drug (Page 14, line 29 – Page 15, line 14).

While the reference does not teach the complete concentration range of the excipients or the weight percentages of the polymeric coating, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to adjust the lag time period of the release of the drug *in vivo* either by increasing or decreasing the lag period with layers of polymeric coating to achieve the similar results. It also would have been obvious to a person of ordinary skill in the art to use bisoprolol hemifumarate as the drug in the formulation being that Buseti et al. taught specifically bisoprolol fumarate but also that the reference taught a wide variety of acceptable drugs for the formulation.

One of ordinary skill in the art would have been motivated to do this to prepare compositions with varying lag times that would delivery the same drug and achieve similar results.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buseti et al. in view of Noda et al. (US 5137733). The teachings of Buseti et al. are discussed

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above. Buseti et al. does not expressly teach the core of the composition as being a nonpareil seed.

Noda et al. teaches a composition wherein the core contains an active agent and is coated with multiple layers of polymers (Col. 2, lines 28-39). The core of the composition is a nonpareil seed having an active agent coated onto it (Col. 6, test Examples 1 and 10). Noda et al. additionally teaches that the active agent core can be formed by a granulation process known in the art (Col. 3, line 63 – Col. 4, line 5). The active agent that can be coated onto the nonpareil core is bisoprolol fumarate (Col. 9, Example 12).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a core of a nonpareil seed that is coated with an active agent and subsequently coated with multiple layers of polymers. Buseti et al. teaches core of an active agent with additional excipients but does not teach a seed coated with an active agent. Noda teaches the same active agent coated onto a nonpareil seed core but additionally teaches that a granulation process can be used to create active agent cores (Col. 3, line 63 – Col. 4, line 5). Both follow the preparation of the core with polymeric coating to create lag times.

One of ordinary skill in the art would have been motivated to do this to prepare a core containing an active agent to regulate particle size of the active agent core (Noda, Col. 4, lines 5-10).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants' arguments filed on July 2, 2001 have been fully considered but they are not persuasive. Applicants argue in their Remarks accompanying the Amendment that the Buseti reference does not teach the required lag times of the instant application. The reference teaches that the same polymeric materials can be used to coat the active agent cores. While the reference does teach the specific lag times of the applicants, Buseti et al. does teach a lag time of 4-9 hours using the same materials as the instant application. The reference further teaches that the times can be adjusted by adjusting the thickness of the layers of polymeric material coated onto the cores. It is the position of the Examiner that the Buseti reference teaches the same composition of an active agent core coated with same polymeric materials as the instant application. As such, similar lag times are implicit from the teachings of the same composition.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
September 20, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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